

REMARKS

Reconsideration of this application is respectfully requested.

In the Office Action, the specification was objected to and claims 1-13 rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-6 U.S. Patent No. 6,632,796, under 35 U.S.C. §§ 112, second paragraph, and 103(a). By the present claim 5 has been canceled without prejudice or disclaimer. Claims 1-4 and 6-13 are pending in this application or at issue.

The issues raised by the Examiner in the Office Action are summarized and addressed below.

Objection to the Specification

The disclosure was objected to because the Examiner contended that the specification failed to update the status of the parent application Serial No. 09/577,858. By the present Amendment, the specification has been amended to update the status of the parent application, U.S. Patent No. 6,632,796.

Therefore, Applicant respectfully submits that the objection to the specification can be withdrawn.

Obviousness-Type Double Patenting Rejection

Claims 1-13 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,632,796 in view of D'Augustine et al. This rejection is respectfully traversed and reconsideration respectfully requested.

Appended hereto is a Terminal Disclaimer in compliance with 37 C.F.R. § 1.312(c) executed by the below-signed Agent of Record in this case and the requisite fee.

Therefore, the obviousness-type double patenting rejection may be withdrawn.

Rejections Under 35 U.S.C. §112, 2nd Paragraph

The rejection of claim 5 under 35 U.S.C. §112 2nd paragraph has been rendered moot by the cancellation thereof without prejudice or disclaimer.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lamonthe et al. (U.S. Patent No. 5,518,733), in combination with D'Augustine et al. (U.S. Patent No. 6,416,779 B1). The Examiner contended that Lamonthe et al. disclosed a vaginal gel containing maltose and an acidic buffer which adjusts the pH of the composition to the range of 5-7. The Examiner admitted that Lamonthe et al. did not disclose the addition of an anti-fungal agent to their composition. The Examiner then cited D'Augustine et al. for disclosing the use of anti-fungal agents such as fluconazole, terconazole and tioconazole for the treatment of vaginitis. The Examiner concluded that one of ordinary skill in the art at the time that the instant invention was made would have been motivated to add an anti-fungal agent to the composition disclosed by Lamonthe et al. in order to prepare a vaginal gel useful for treating fungal infections. This rejection is respectfully traversed and reconsideration respectfully requested.

The present invention as embodied in claims 1-4 and 6-13 is directed to a composition and method for treating a patient suffering from vaginitis, a disturbance of the vaginal bacterial flora or bacterial vaginosis, wherein said vaginitis, disturbance of vaginal bacterial flora or bacterial vaginitis are accompanied with a reduction of the number of Gram-positive bacilli. Neither of the cited references alone or in combination disclose or suggest this composition or method.

Lamonthe et al. disclosed that a cosmetic composition containing maltose can promote the growth of some microorganisms on skin or in the vagina. Lamonthe et al. also disclosed that their composition may be in the form of a vaginal gel. However, the composition was not said to be useful for treating any diseases but was said to be mainly for promoting the growth of Gram-

positive cocci, such as *Micrococcus kristinae*, *Micrococcus sedentarius*, *Staphylococcus capitis*, etc. It is well known to those of ordinary skill in the art that although these bacteria may have a beneficial effect on the skin, they are never beneficial when found in the vagina. Appended hereto as Exhibits 1-3 are Abstracts from three papers which emphasize this point:

1) Rosenstein, I.J. et al., Bacterial vaginosis in pregnancy: distribution of bacterial species in different gram-stain categories of the vaginal flora. J Med Microbiol 1996 1996 Aug; 45(2):120-6; 2) Hughes, V.L. et al., Microbiologic characteristics of Lactobacillus products used for colonization of the vagina. Obstet Gynecol 1990 Feb; 75(2):244-8; 3) McLean, N.W. et al., Characterization and selection of a Lactobacillus species to re-colonize the vagina of women with re-current bacterial vaginosis. J Med Microbiol 2000 Jun; 49(6):543-52).

In contrast, the present invention is directed to treating vaginal diseases characterized by a reduction of Gram-positive cocci by promoting the selective growth of Gram-positive bacilli in the vagina as set forth in col. 24, lines 7-8. Bacteria disclosed in Lamonthe et al. are not the same as those disclosed in the instant application. Lamonthe only discloses cocci not bacilli. Lamonthe et al. never mentioned anything pertaining to vaginitis and disturbance of vaginal bacterial flora or bacterial vaginosis accompanied with a reduction in the number of Gram-positive bacilli as set forth in the present claims.

D'Augustine adds nothing to Lamonthe that would lead one of ordinary skill in the art to the present invention as embodied in claims 1-4 and 6-13 herein. D'Augustine discloses a method for treating candidiasis with anti-fungal agents as set forth in col. 21, line 47. In contrast, the claims pending in the above-identified application are specifically directed to treating vaginitis, a disturbance of the vaginal bacterial flora or bacterial vaginosis, wherein said vaginitis, disturbance of vaginal bacterial flora or bacterial vaginosis are accompanied with a reduction in the number of Gram-positive bacilli not for treating Candidiasis vaginitis. Therefore, the diseases disclosed in D'Augustine belong to a different illness category than those of the instant invention.

Conclusion

Claims 1-4 and 6-13 are in a condition for allowance.

In view of the above amendments and remarks, reconsideration of this application and issuance of a Notice of Allowance for claims 1-4 and 6-13 is earnestly solicited.

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Respectfully submitted,

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